

TABLE—APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline Number	Data requirement	Use pattern		Test substance	Test Note No.
		Occupational	Residential		
875.1100 .....	Dermal outdoor exposure	R	R	TEP	1, 2, 3
875.1200 .....	Dermal indoor exposure	R	R	TEP	1, 2, 4
875.1300 .....	Inhalation outdoor exposure	R	R	TEP	1, 2, 3
875.1400 .....	Inhalation indoor exposure	R	R	TEP	1, 2, 4
875.1500 .....	Biological monitoring	CR	CR	TEP	1, 2
875.1600 .....	Data reporting and calculations	R	R	TEP	5
875.1700 .....	Product use information	R	R	TEP	--

(e) *Test notes.* The following notes apply to the data requirements in the table to paragraph (d) of this section:

1. Protocols must be submitted for approval prior to the initiation of the study. Details for developing protocols are available from the Agency.

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation exposure data, provided the human pharmacokinetics of the pesticide and/or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to actual dose.

3. Data are required if the product is applied outdoors.

4. Data are required if the product is applied indoors.

5. Data reporting and calculations are required when handler exposure data are submitted.

#### § 158.1050 Post-application exposure—general requirements.

(a) If EPA determines that industrial standards, such as the workplace standards set by the Occupational Safety and Health Administration, provide adequate protection for a particular pesticide use pattern, post-application exposure data may not be required for that use pattern. Applicants should consult with the Agency on appropriate testing before the initiation of studies.

(b) The Agency may accept surrogate exposure data from other sources to satisfy post-application exposure data requirements if the data meet the basic quality assurance, quality control, good laboratory practice, and other scientific needs of EPA. In order to be acceptable, among other things, the

Agency must find that the surrogate exposure data have adequate information to address post-application exposure data requirements and contain adequate replicates of acceptable quality data to reflect the specific use prescribed on the label and the post-application activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information. The Agency will consider using such surrogate data for evaluating human exposure on a case-by-case basis.

#### § 158.1060 Post-application exposure—criteria for testing

Exposure data described in § 158.1070(d) are required based upon toxicity and exposure criteria. Data are required if a product meets, as determined by the Agency, either or both of the toxicity criteria in paragraph (a) of this section and either or both of the exposure criteria in paragraph (b) of this section.

(a) *Toxicity criteria.* (1) Evidence of potentially significant adverse health effects have been observed in any applicable toxicity study.

(2) Scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from post-application exposure to the pesticide.

(b) *Exposure criteria.* The need for data from potential exposure resulting from situations not covered by this paragraph should be discussed with the Agency.

(1) *For outdoor uses.* (i) Occupational human post-application exposure to

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pesticide residues on plants or in soil could occur as the result of cultivation, pruning, harvesting, mowing or other work-related activity. Such uses include agricultural food, feed, and fiber commodities, forest trees, ornamental plants, and turf grass.

(ii) Residential human post-application exposure to pesticide residues on plants or in soil could occur. Such uses may include turf grass, fruits, vegetables, and ornamentals grown at sites, including, but not limited to, homes, parks, and recreation areas.

(2) *For indoor uses.* (i) Occupational human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at agricultural or commercial sites, such as, but not limited to, agricultural animal facilities and industrial or manufacturing facilities.

(ii) Residential human post-application exposure to pesticide residues could occur following the application of the pesticide to indoor spaces or surfaces at residential sites, such as, but not limited to homes, daycare centers, hospitals, schools, and other public buildings.

### § 158.1070 Post-application exposure data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to

determine the post-application data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Occupational use patterns include products classified under the general use patterns of terrestrial food crop, terrestrial feed crop, terrestrial nonfood use, aquatic food, aquatic nonfood use, forestry, greenhouse food, greenhouse nonfood, indoor food, and indoor nonfood. Occupational use patterns also include commercial (“for hire”) applications to residential outdoor and indoor sites.

(2) Residential use patterns include residential outdoor use and indoor residential use. These use patterns are limited to nonoccupational, *i.e.*, nonprofessional, pesticide applications.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; TEP=Typical end-use product.

(d) *Table.* The data requirements listed in the following table pertain to pesticide products that meet the testing criteria outlined in § 158.1060. The table notes are shown in paragraph (e) of this section.

TABLE—POST-APPLICATION EXPOSURE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern		Test Substance	Test Note No.
		Occupational	Residential		
875.2100 .....	Dislodgeable foliar residue and turf transferable residues	R	R	TEP	1, 2, 3, 4, 5
875.2200 .....	Soil residue dissipation	R	CR	TEP	1, 2, 6, 7
875.2300 .....	Indoor surface residue dissipation	R	R	TEP	1, 2, 8, 9
875.2400 .....	Dermal exposure	R	R	TEP	1, 2, 10, 11, 12
875.2500 .....	Inhalation exposure	R	R	TEP	1, 10, 11, 12
875.2600 .....	Biological monitoring	CR	CR	TEP	1, 12, 13
875.2700 .....	Product use information	R	R	TEP	--
875.2800 .....	Description of human activity	R	R	TEP	--
875.2900 .....	Data reporting and calculations	R	R	TEP	14
875.3000 .....	Nondietary ingestion exposure	NR	R	TEP	1, 11, 15